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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/809,214 | 03/25/2004 | Fiona E. Black | 01-00007 | 2483 |

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| EXAMINER |
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LUM, LEON YUN BON

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| ART UNIT | PAPER NUMBER |
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1641

DATE MAILED: 07/26/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

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|------------------------------|-------------------------------|------------------------------|--|
| Office Action Summary | Application No. 10/809,214 | Applicant(s) BLACK ET AL. | |
| | Examiner Leon Y. Lum | Art Unit 1641 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 13 May 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3,6,8-11 and 34-60 is/are pending in the application.
- 4a) Of the above claim(s) 38-50 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,3,6,8-11 and 34-37 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

1. The amendment filed 13 May 2005 is acknowledged and has been entered.

Election/Restrictions

2. Applicant's election without traverse of claims 1-11 in the reply filed on 13 May 2005 is acknowledged. See page 13, last paragraph to page 14, 1st paragraph.
3. Newly submitted claims 38-60 are directed to an invention that is independent or distinct from the invention originally claimed for the reasons set forth in the restriction requirement of the previous Office Action. See pages 2-7.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 38-60 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

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A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 1, 3, 6, 8-11 and 34-35 are rejected under 35 U.S.C. 102(b) as being anticipated by Walt et al (US 6,237,410 B1).

In the instant claims, Walt et al reference teaches a substrate comprising a bundle 202 with wells 250 (i.e. substrate) that retains microspheres (i.e. substrate comprises a particle), wherein microsphere 10 has bioactive agent 12 thereon (i.e. biopolymer probe attached to said substrate), and wherein a thin film of polyethylene glycol can be formed over the microspheres to hold the microspheres in place (i.e. a stabilization polymer layer on said substrate, wherein said stabilization polymer layer coats said biopolymer probe; non-naturally occurring polyethylene glycol). See column 5, line 61 to column 6, line 3; column 7, lines 42-49; column 16, line 66 to column 17, line 10; column 17, line 47 to column 18, line 2; and Figures 1 and 5. In addition, Walt et al teach that bioactive agents are covalently attached to the beads (i.e. biopolymer probe is covalently attached to said substrate). See column 11, lines 63-64.

Furthermore, Walt et al teach that the substrate contains arrays of beads with different bioactive agents (i.e. array of different biopolymer probes). See column 4, lines 59-66.

With regards to claim 3, Walt et al teach that the microsphere array 100 is attached to the distal end 212 of a fiber optic bundle 202 (i.e. substrate comprises a fiber optic array). See column 16, lines 21-29 and Figure 4.

With regards to claims 8-9, Walt et al teach that the bioactive agents 12 (i.e. biopolymer) can be polynucleotides or polypeptides. See column 7, line 60 and column 8, line 37.

With regards to claim 34, Walt et al teach that the detection of binding is obtained when fluorescent dyes bind to target that has bound to the bioactive agents, thereby indicating that the label is not on the bioactive agent (i.e. biopolymer probe lack extrinsic labels). See column 15, lines 41-54; and Figure 3.

With regards to claim 35, since Walt et al teach that polyethylene glycol is permeable to aqueous species, it would not prevent the probe from producing an optical signal.

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.

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3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

8. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

9. Claims 36-37 are rejected under 35 U.S.C. 103(a) as being unpatentable over Walt et al (US 6,237,410 B1) in view of Lennox et al (US 5,955,379).

Walt et al reference has been disclosed above, but fails to teach that said biopolymer probes comprise extrinsic labels.

Lennox et al reference teaches displacement assays, in order to determine ligand-receptor binding affinity. See column 1, line 63 to column 2, line 3.

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the apparatus of Walt et al with displacement assays, as taught by Lennox et al, in order to determine ligand-receptor binding affinity. The displacement assays of Lennox et al would therefore provide the advantage of determining the binding relationship between the bioactive agent (i.e. probe) and targets of Walt et al.

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One of ordinary skill in the art at the time of the invention would have had reasonable expectation of success in including the displacement assay of Lennox et al, in the apparatus of Walt et al, since Walt et al teach a device to determine binding between two biomolecules, and the displacement assay of Lennox et al is one type of technique that determines binding between two biomolecules.

With regards to claim 37, since Walt et al teach that polyethylene glycol is permeable to aqueous species, it would not prevent the probe from producing an optical signal.

Response to Arguments

10. On page 11 of the Remarks, filed 13 May 2005, with regards to claim 1, Applicants argue that Walt et al reference does not describe "an array of different biopolymer probes covalently attached to said substrate" since the polyethylene glycol holds the beads to the substrate by film formation rather than formation of a covalent bond between bead and well. In addition, Applicants argues that even if the beads can be taken to be the claimed substrate, each bead in Walt et al has a single species of biopolymer probe attached and therefore the reference does not satisfy the requirement of comprising an array of different biopolymer probes covalently attached to said substrate.

Applicant's arguments have been fully considered but they are not persuasive. The Examiner takes the position that the microspheres 10 and bundle 202 in Walt et al

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are considered to be the entire substrate as claimed (see column 16, line 66 to column 17, line 10; and Figure 5). The disclosure that the polyethylene glycol is used to immobilize the microspheres does not preclude the microsphere from being part of the substrate. Just as a flat plane substrate can include a plurality of different layers, the device of Walt et al includes a microsphere layer and a bundle layer. Therefore, since it is established that the microspheres and bundle are considered to be a substrate as a whole, and since Walt et al disclose that the device comprises an array of microspheres and each microsphere comprises a different bioactive agent that is covalently immobilized (see rejection supra), Walt et al thoroughly anticipates the disputed limitation of claim 1.

11. Applicant's arguments, see page 12 of the Remarks, with respect to the provisional double patenting rejection have been fully considered and are persuasive. The provisional double patenting rejection of claims 1, 3, 6, 8-11, has been withdrawn.

Conclusion

12. The prior art made of record and not relied upon is considered to be pertinent to Applicant's disclosure:

Agrawal et al (US 2003/0224506 A1) teach a protective coating that may be used to encapsulate a media to keep probes on a microarray from denaturing.

13. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Leon Y. Lum whose telephone number is (571) 272-2878. The examiner can normally be reached on weekdays from 8:00am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on (571) 272-0823. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Leon Y. Lum
Patent Examiner
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07/22/05